



IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Before the Board of Patent Appeals and Interferences

In re the Application of

Amar LULLA et al.

Serial No.: 10/617,850

Filed: July 14, 2003

For: SPACER DEVICE FOR INHALER

Group Art Unit: 3743

Examiner: N. Patel

Confirmation No.: 7989

APPEAL BRIEF

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TECHNOLOGY CENTER R3700

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Date: June 27, 2006

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I. REAL PARTY IN INTEREST

The real party in interest is the assignee of the applicants' interest, CIPLA LIMITED, of Mumbai, India, having a principal address of Mumbai Central, Mumbai, India 400 008.

II. RELATED APPEALS AND INTERFERENCES

There are no related appeals or interferences known to Appellants, Appellants' legal representative or the assignee, which will directly affect, or be directly affected by, or have a bearing on, the Board's decision in the pending appeal.

III. STATUS OF CLAIMS

The application was originally filed with fourteen claims but, of those, only claims 1 and 5-13 remain pending and are the subject matter for this appeal. Claims 2-4 and 14 have previously been cancelled.

IV. STATUS OF AMENDMENTS

No amendments after the Final Rejection have been made.

V. SUMMARY OF CLAIMED SUBJECT MATTER

1. Independent Claim 1

Independent claim 1 sets forth a spacer device (specification, page 1, first paragraph and Fig. 1) to be used for the oral administration of a volatile medium containing a medicament such as would be found in an aerosol medicament reservoir (Fig. 121) Fig. 5. The source or reservoir of medicament is not a part of the invention claimed in claim 1. The spacer device comprises a chamber (120 - Fig. 1) having an inlet (105 - Fig. 1) to admit a measured dose of medicament and an outlet (106) to be received in the mouth of the patient, wherein the chamber is made of a polyamide and comprises two frustoconical members (101; 102 - Fig. 2) assembled together coaxially at divergent ends (107, 108 - Fig. 2) wherein said inlet (105 - Fig. 1) and said outlet (106 -

Fig. 1), respectively, are at opposed convergent ends of said first and second conical members 101, 102, respectively (Fig. 1).

2. Independent Claim 7

Independent claim 7 sets forth a spacer device (specification, page 1, first paragraph and Fig. 1) to be used for the oral administration of a volatile medium containing a medicament such as would be found in an aerosol medicament reservoir (Fig. 121) Fig. 5. The source or reservoir of medicament is a part of the invention claimed in claim 7. The spacer device comprises a chamber (120 - Fig. 1) having an inlet (105 - Fig. 1) to admit a measured dose of medicament and an outlet (106) to be received in the mouth of the patient, wherein the chamber is made of a polyamide and comprises two frustoconical members (101, 102 - Fig. 2) assembled together coaxially at divergent ends (107, 108 - Fig. 2) wherein said inlet (105 - Fig. 1) and said outlet (106 - Fig. 1), respectively, are at opposed convergent ends of said first of conical members 101, 102 (Fig. 1). Claim 7 also requires locking means expressed as a means plus function limitation. The locking means are shown at 109 (Fig. 1, 2). This locking means 109 can be a notch and projection to ensure that the two frustoconical members (101, 102) have been properly assembled (See, page 4 of the specification, lines 12-14).

3. Independent Claim 8

Independent claim 8 sets forth a spacer device (specification, page 1, first paragraph and Fig. 1) to be used for the oral administration of a volatile medium containing a medicament such as would be found in an aerosol medicament reservoir (Fig. 121) Fig. 5. The source or reservoir of medicament is a part of the invention claimed in claim 8. The spacer device is made of a polyamide and comprises two frustoconical members (101, 102 - Fig. 2) assembled together coaxially at divergent ends (107, 108 - Fig. 2) wherein said inlet (105 - Fig. 1) and said outlet (106 - Fig. 1), respectively, are at opposed convergent ends of said first of conical members 101, 102 (Fig. 1). Claim 8 also includes a limitation in a means plus function clause, i.e., "means whereby the user can inhale the said medium from the spacer device." As shown in Fig. 5, the inhaler comprises a source of medicament in an aerosol medicament reservoir (121) wherein a dose of inhalant suspension is pumpable into chamber 120 (Fig. 1) through inlet (105). The patient then places outlet 106 in the

mouth and inhales steadily to draw the suspension into the lungs of the user (See, specification, page 4, lines 15-19).

4. Independent Claim 12

Independent claim 12 is directed to a method of administering a dose of a fine particulate medicament suspended in a gas (specification, paragraph bridging pages 2-3). The method comprises injecting the medicament into a polyamide chamber (120 - Fig. 1) having an inlet (105 - Fig. 1) to admit a measured dose of medicament and an outlet (106) to be received in the mouth of the patient, wherein the chamber is made of a polyamide and comprises two frustoconical members (101, 102 - Fig. 2) assembled together coaxially at divergent ends (107, 108 - Fig. 2) wherein said inlet (105 - Fig. 1) and said outlet (106 - Fig. 1), respectively, are at opposed convergent ends of said first of conical members 101, 102 (Fig. 1). As shown in Fig. 5, the inhaler comprises a source of medicament in an aerosol medicament reservoir (121) wherein a dose of inhalant suspension is pumped into chamber 120 (Fig. 1) through inlet (105). The patient then places outlet 106 in the mouth and inhales steadily to draw the suspension into the lungs of the user (See, specification, page 4, lines 15-19).

VI. ISSUES TO BE REVIEWED ON APPEAL

The rejection set forth in the Final Rejection mailed December 28, 2005, merely incorporates by reference the rejections of previously presented claims 1, 5, 8, 9, 10, 12, and 14 (sic - 13) [as 14 was cancelled], and original claims 6 and 10 as stated in the Office Action dated June 3, 2005. As stated in the Office Action of June 3, 2005, claims 1, 5, 6 and 8-13 stand rejected under 35 U.S.C. §103(a) as being unpatentable over Schmidt et al (U.S. Publication 2002/0026935) in view of Armer (U.S. Patent 6,095,141) and further in view of Berg (U.S. Patent 6,435,176). Claim 7 stands rejected under 35 U.S.C. §103(a) as being unpatentable over Schmidt as applied to claims 1, 5, 6 and 8-13 above and further in view of Hallworth et al (U.S. Patent 4,206,758).

VII. ARGUMENT

A. The rejection under 35 U.S.C. §103(a) as being unpatentable over Schmidt et al in view of Armer et al and further in view of Berg

1. The presence of polyamide in independent claims 1, 8 and 12

The claims set forth, in combination, a spacer device for the oral administration of a volatile medium containing a medicament, which device comprises a chamber having an inlet to admit a measured dose of medicament and an outlet to be received in the mouth. This is the only limitation that the Examiner has alleged that Schmidt teaches. See, for example, the first full paragraph on page 3 of the Office Action of June 3, 2005, “Schmidt discloses the applicant’s invention as claimed with the exception of providing a chamber that is made from polyamide that comprises two frustoconical members assembled coaxially at divergent ends, the inlet and outlet being respectively at opposed ends.” The secondary references, Armer et al and Berg et al are apparently cited to show the features lacking in Schmidt. However, this is not the claimed invention as alleged by the Examiner. The Examiner must consider the invention “as a whole” and may not parse it into components. See, 35 U.S.C. §103(a). It was quite clear from the application as filed (specification, page 2, lines 17-23) that the use of polyamides unexpectedly resulted in improved transmission of the particulate medicament to the user, i.e., the medicament was not retained in or coated on the spacer or its component parts and was part of the invention; See, test results in table on page 5 of the specification.

Paragraph [0102] of Schmidt describes that “the canister-holding portion, the chamber housing and the end cap formed of a suitable hard, durable plastic, such as polypropylene.” As is well known in chemistry, polypropylene is an olefin and is not a polyamide, as claimed. Appellants had previously argued that the polyamide is not only unexpectedly different over the materials compared in their original disclosures as reported in the table on page 5 of the specification, but is also unexpectedly superior to polypropylene. Appellants respectfully direct the Board’s attention to page 5 of the amendment filed on March 14, 2005, which states (in relevant part):

“As the present invention is a selection invention, wherein the specific material, i.e., polyamide, has been found to provide unexpected advantages not provided by other plastic materials, applicants respectfully present that the selection of polyamide from

the list of possible materials that have been obvious. Unexpected superior properties exhibited when polyamide is selected as the material for the spacer are demonstrated in the affidavit under 37 C.F.R. §1.132, submitted August 6, 2003.

That Affidavit (attached in Evidence Appendix (IX) by Sunita Sule describes the results of an Aerodynamic test assessment as described in this (and parent application U.S. Serial No. 09/857,707 (the “707 of application”) which the present application is a continuation.

As the Declarant states at paragraph 3, “the following table is an accurate representation of the data resulting from the above-described test [Aerodynamic assessment test],” and includes polypropylene (the material of Schmidt) which produced a respirable fraction of only 50% whereas polyamide (as claimed) provided a respirable fraction of 65%. Declarant concludes from the results of the tests “that when polyamide is used as a material for the spacer, an unexpectedly superior property results” compared to the use of a polyolefin, such a polypropylene.

The Examiner ignores these results and relies solely on the alleged *prima facie* case of obviousness made by the combination of the various materials found in Armer (including polyamide) for the polypropylene of Schmidt et al. This is contrary to the established authority of the Federal Circuit, as expressed in In re Lilly & Co., 902 F.2d 943, 945; 14 USPQ2d 1741, 1743 (1990), citing In re Piasecki, 745 F.2d 1468, 1472, 223 USPQ 785, 788 (Fed. Cir. 1984):

“When *prima facie* obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over An earlier decision should not, as it was here, be considered as set in concrete, and applicant’s rebuttal evidence then be evaluated only on its knockdown ability Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself”

(quoting In re Rinehart, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976)).

Thus, even if Schmidt were combined with Armer et al which teaches that “housing 12 advantageously is formed of a plastic such as polyamide . . . polypropylene . . .”, Armer does not recognize any distinction flowing from the specific selection of a plastic from his laundry list of plastic materials. Thus, even if the polypropylene of Schmidt et al were substituted by polyamide as in Armer, such a proposed *prima facie* case of obviousness is rebutted by the showings in the Sule Declaration which show an unexpectedly superior amount of medicament being transmitted to the patient which can be obtained by using polyamide instead of the olefin, polypropylene.

2. The shape of the spacer

Claims 1 and 12 also includes the limitation “wherein the chamber . . . comprises two frustoconical members assembled together coaxially at their divergent ends” and claim 8 contains the limitation “spacer device . . . comprises two frustoconical members assembled together coaxially at their divergent ends.” The Office Action states that it would have been obvious to modify the device of Schmidt et al to have the shape as taught by Berg et al, i.e., two members that are assembled together coaxially at their divergent ends” and to further modify the device such that the chambers are frustoconical in shape.

The device described by Berg et al comprises a chamber which is constructed from one “slightly conical tapering” and one “substantially hemispherical” member. Accordingly, the device of Berg et al, although being the closest cited prior art, contains, at best, only a single frustoconical member. Of course, it is clear from the drawing Figs. of Schmidt et al that his chamber is elliptical. Thus, there is no suggestion in the reference to make the proposed combination of Schmidt and Berg and then further modify that combination to make the claimed chamber (or spacer).

The Board is well aware that its reviewing courts have often advised it that it can satisfy the burden of establishing a *prima facie* case of obviousness “only by showing some objective teaching in either the prior art, or knowledge generally available to one of ordinary skill in the art, that ‘would lead’ that individual ‘to combine the relevant teachings of the reference’” Ex parte Levengood, 28 USPQ 2d 1300, 1302 (BPAI 1993).

Here, clearly lacking the motivation in the cited prior art, and lacking any suggestion of knowledge generally available to one of ordinary skill in the art, the Examiner turns to appellants’ own disclosure as providing the suggestion to make the modification (See, Final Rejection, page 3, lines 10-13, “Applicant’s (sic - applicants’) statement on page 3 of the specification wherein the applicant states (sic - applicants’ state) that “. . . the spacer device can be of various shapes and construction.”

Clearly, appellants’ disclosure is not part of the prior art and is, therefore, not available to support the purported *prima facie* case of obviousness; In re Vaeck, 20 USPQ 2d 1438, 1443 (Fed. Cir. 1991):

“Where claimed subject matter has been rejected as obvious in view of a combination of prior art references, a proper analysis under §103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success. *See In re Dow Chemical Co.*, 837 F.2d 469, 473, 5 USPQ2d 1529, 1531 (Fed. Cir. 1988). Both the suggestion and the reasonable expectation of success must be founded in the prior art, not in the applicant’s disclosure. *Id.*

Thus, the Examiner’s reliance on Appellants’ specification is not permissible in order to establish a *prima facie* case of obviousness.

C. The recitation of frustoconical members forming the chamber of claims 1 and 12 (or the “spacer device” of independent claim 8)

The Examiner further attempts to ignore the plain language of the “frustoconical members” forming the chamber (or spacer) as recited in the claims.

In response to appellants’ arguments as set forth in the Final Rejection, page 2, the Examiner argues that “it is noted that the features relied upon which applicant relies (i.e., “two members forming a chamber”) are not recited in the rejected claim(s).” Appellants respectfully disagree.

As set forth in independent claims 1 and 12 (and, by statute, independent claims 5, 6, 10-11 and 13) (35 U.S.C. §112, fourth paragraph), the chamber is expressly described as “two frustoconical members assembled together coaxially at divergent ends.” Thus, the Examiner’ allegation that the claims do not recite the limitations argued is clearly erroneous and should be reversed on that basis alone. Similarly, independent claim 8 also recites the same limitation, i.e., the spacer device . . . comprising two frustoconical members assembled together coaxially at their divergent ends” and these independent claims (together with claim 9 dependent thereon) are also free of the Examiner’s sole argument that the claims do not recite these limitations. Accordingly, each of the rejection of claims 1, 5, 6 and 8-13 should be reversed because the Examiner has indicated he has not considered the express limitations that the chamber (or spacer device) are made of frustoconical members joined together at the divergent ends and has overlooked and/or refused to consider the teachings of the Sule Declaration which demonstrate that, assuming *arguendo*, a *prima facie* case of substitution of

polyamide for polypropylene exists, that such substitution has been rebutted by appellants with a showing of unexpected results as contained in the Sule Declaration, which the Examiner has not properly considered anew. Of course, it is evident, appellants used a standard test, i.e., the Aerodynamic assessment of fine particle fraction as per BP Addendum 1996 using apparatus A and 10 doses) as set forth therein. Such a test for fine particle assessment approximate an *in vitro* estimate of the distribution of the drug in the human respiratory track; See, specification, page 4, line 21 through the last line of page 5.

In layman's terms, this means that approximately 30% more medicament

$$(65 - 50 = 15 \div 50 = .3 \times 100\% = 30\%)$$

means that the reservoir of the inhaler can be made smaller because 30% more medicament is being administered to the patient or, alternatively, the same sized reservoir will provide more doses per fixed amount of medicament. As a comparison, an inhaler 30 as in Schmidt providing 30 doses could deliver almost 40 doses if modified by using a spacer device according to the present invention.

D. The rejection of claim 7 under 35 U.S.C. 103(a) as being unpatentable over Schmidt (U.S. Publication 2002/0026935) as applied to claims 1, 5, 6 and 8-13 above and further in view of Hallworth (U.S. Patent 4,206,758)

Claim 7 recites that the "chamber is made of a polyamide and comprises two frustoconical members assembled together coaxially at divergent ends"

As noted hereinabove, Schmidt teaches an inhaler device, but his disclosure in no way teaches, suggests or otherwise discloses a chamber "made of a polyamide and comprises two frustoconical members assembled together coaxially at divergent ends" As noted hereinabove in connection with the rejection of claims 1 and 12, the Examiner conceded that Schmidt does not teach a chamber "that is made from polyamide, that comprises two first frustoconical member assembled together coaxially at divergent ends" See, for example, page 3, lines 1-4 of the Office Action mailed June 3, 2005.

Accordingly, the combination of Schmidt with Hallworth et al could not possible establish a *prima facie* case of obviousness for the claimed invention because Hallworth is cited for "discloses

a device for dispensing medicaments, but does provide a locking means that are provided to lock the two members together in assembled position,” but is not alleged to cure the other deficiencies of Schmidt et al.

As set forth in the disclosure of Hallworth, e.g., column 2, lines 36-40, with reference to Figs. 1-2 therein, the inhalation device of Hallworth “comprises a cylindrical body shell 1 which is conveniently, but not essentially, of a transparent plastics material.” There is no disclosure of a chamber formed of frustoconical members nor any identification that the plastics material is a polyamide. As these limitations are also lacking in Schmidt, the proposed combination of Schmidt and Hallworth cannot possibly establish a *prima facie* case of obviousness for independent claim 7.

It is evident from the Final Rejection, page 2, lines 13-15, that the Examiner has not considered all the limitations recited in the claims, especially that the “spacer device . . . comprises two frustoconical members assembled together coaxially at their divergent ends.” Moreover, in order to meet this limitation not found in the cited references or knowledge in the prior art, the Examiner impermissibly relies on appellants’ own disclosure in violation of established authority, In re Vaeck, Id.

VIII. CONCLUSION

For all the foregoing reasons, appellants respectfully submit that the Examiner has failed to establish a *prima facie* case of obviousness for the claimed invention and, even assuming, *arguendo*, that a *prima facie* case has been made out for one or more claims, the Examiner fails to consider the evidence of record rebutting the alleged obviousness of the invention, thereby satisfying appellants’ burden.

No part of appellants’ disclosures forms part of the “prior art” and no part of it can be used to provide the suggestion and/or motivation that would have impelled one of ordinary skill in the art to do what appellants have done in arriving at their invention.

Lastly, the Examiner has not considered all the limitations of appellants’ claims, especially that the claims expressly recite “chamber . . . comprises two frustoconical members assembled together coaxially at their divergent ends” (claims 1, 7 and 12) or, alternatively, that the “spacer

device . . . comprises two frustoconical members assembled together coaxially at their divergent ends" (claim 7).

Accordingly, for all the foregoing reasons, reversal of all rejections are respectfully requested.

IX. CLAIMS APPENDIX

An appendix containing a copy of the claims involved in the appeals is attached.

X. EVIDENCE APPENDIX

A copy of the Affidavit of Sunita Sule submitted under 37 C.F.R. §1.132 is attached.

XI. RELATED PROCEEDINGS APPENDIX

Not applicable.

Respectfully submitted,



TPP/mat

Attorney Docket No.: TPP 31402A

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CLAIMS APPENDIX

1. A spacer device for the oral administration of a volatile medium containing a medicament, which device comprises a chamber having an inlet to admit a measured dose of medicament and an outlet to be received in the mouth, wherein the chamber is made of a polyamide and comprises two frustoconical members assembled together coaxially at divergent ends, said inlet and outlet being respectively at opposed convergent ends.

2-4. (Cancelled)

5. A device according to claim 1, wherein the divergent end of one member is received in the divergent end of the other member to provide a substantially air-tight seal.

6. A device according to claim 5, wherein the said divergent ends have complementary stepped surfaces to provide a close air-tight fit.

7. A spacer device for the oral administration of a volatile medium containing a medicament, which device comprises a chamber having an inlet to admit a measured dose of medicament and an outlet to be received in the mouth, wherein the chamber is made of a polyamide and comprises two frustoconical members assembled together coaxially at divergent ends, said inlet and outlet being respectively at opposed convergent ends, wherein locking means are provided to lock the two members together in assembled condition.

8. An inhaler for dispensing a measured dose of a medicament in a volatile medium, a spacer device for receiving the medium, and means whereby the user can inhale the said medium from the spacer device, wherein the spacer device is made of polyamide and comprises two frustoconical members assembled together coaxially at their divergent ends, said inlet and outlet being respectively at the opposed convergent ends.

9. An inhaler and spacer device according to claim 8, wherein the spacer device is for the oral administration of a volatile medium containing a medicament, which device comprises a chamber having an inlet to admit a measured dose of medicament and an outlet to be received in the mouth.

10. The use of a non-metallic antistatic spacer device according to claim 1, for the inhalation of a particulate medicament in a volatile medium.

11. The use according to claim 10, wherein there is substantially little or no deposit of medicament on the inside of the device.

12. A method of administering a dose of a fine particulate medicament suspended in a gas, which comprises injecting said dose into a polyamide chamber, the chamber comprising two frustoconical members assembled together coaxially at their divergent ends, said inlet and outlet being respectively at the opposed convergent ends, and inhaling the dose from the chamber.

13. A method according to claim 12, wherein the chamber device is in a device having an inlet to admit a measured dose of medicament and an outlet to be received in the mouth.

14. (Cancelled)

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EVIDENCE APPENDIX

U.S. Appl. No. 10/617,850



UNITED STATES PATENT AND TRADEMARK OFFICE

In re the Application of

Amar LULLA, et al.

Art Unit: 3761

Serial No. 09/857,707

Examiner: T. Mitchell

Filed: June 8, 2001

For: SPACER DEVICE FOR INHALER

AFFIDAVIT UNDER 37 CFR § 1.132

The Honorable Commissioner
of Patents and Trademarks
Washington, D.C. 20231

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JUL 05 2006

Sir:

TECHNOLOGY CENTER H3700

I, SUNITA SULE, declare to the following.

1. I am familiar with the specification of U.S. Application No. 09/857,707 (the '707 Application) and International Publication No. 93/111817.
2. Under my direction, an Aerodynamic assessment test, as described in the '707 Application, of the fine particle fraction as per BP Addendum 1996 using apparatus A and ten doses was conducted.
3. The following table is an accurate representation of the data resulting from the above-described test, when the different materials are used for the spacer:

<u>Material</u>	<u>Respirable Fraction</u>
Polycarbonate	40-50%
Polypropylene	50%
Polyamide	65%
4. The above table demonstrates that when polyamide is used as the material for the spacer, an unexpectedly superior property results.

5. It is my belief that other polyolefins, such as polyethylene, would give results similar to, or not as good as, that obtained for polypropylene.
6. I, further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the this application or of any reissue patent to issue thereon.

A handwritten signature in cursive script, appearing to read "Shule", is written over a horizontal line.

Date 14-10-2002.

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RELATED PROCEEDINGS INDEX

N/A.